

Notice of Allowability

Application No.

10/560,116

Examiner

Hemant Khanna

Applicant(s)

WOLLIN, STEFAN-LUTZ

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 01/17/2007.
2. ☒ The allowed claim(s) is/are 3-5.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Sheldon McGee on March 27, 2007.

The Claims have been amended as follows:

In Claim 3, line 7, the phrase "a pulmonary surfactant" has been deleted and the word ~~Lusupultide~~—inserted therefor

In Claim 3, line 8, the word "SILDENAFIL" has been deleted and the word ~~Sildenafil~~—inserted therefor.

In Claim 3, line 8, the "." has been deleted and the phrase ~~—wherein the disease in which pulmonary surfactant malfunction and/or phosphodiesterase 5 (PDE5) activity is detrimental is selected from the group consisting of COPD, bronchitis, bronchial asthma, pulmonary fibroses, emphysema, interstitial pulmonary disorders, pneumonia, ALI, ARDS and asthma bronchiale~~—inserted therefor.

In Claim 4, line 1, the phrase "an effective amount of" has been deleted and the word ~~the~~ inserted therefor

In Claim 4, line 2, the phrase "a pulmonary surfactant" has been deleted and the word ~~Lusupultide~~ inserted therefor

In Claim 4, line 2, the word "SILDENAFIL" has been deleted and the word ~~Sildenafil~~ inserted therefor.

In Claim 4, line 3, the word "is" has been deleted and the word ~~are~~ inserted therefor.

In Claim 4, line 4, the phrase "to a patient in need thereof" has been deleted.

In Claim 5, line 1, the phrase "an effective amount of" has been deleted and the word ~~the~~ inserted therefor

In Claim 5, line 2, the phrase "a pulmonary surfactant" has been deleted and the word ~~Lusupultide~~ inserted therefor

In Claim 5, line 2, the word "SILDENAFIL" has been deleted and the word ~~Sildenafil~~ inserted therefor.

In Claim 5, line 4, the phrase "close in time or remote in time" has been deleted.

In Claim 5, line 4, the phrase "whatever to a patient in need thereof" has been deleted.

Claims 7, 8 and 15 have been cancelled.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance:

The claims are drawn to a method for treating or reducing the onset of symptoms of a disease in which pulmonary surfactant malfunction and/or phosphodiesterase 5 (PDE5) activity is detrimental, or treating or reducing the severity of a disease in which pulmonary surfactant malfunction and/or phosphodiesterase 5 (PDE5) activity is detrimental in a patient comprising administering intratracheally or intrabronchially to a patient in need thereof an effective amount of (1) Lusupultide and (2) Sildenafil or a pharmaceutically acceptable salt thereof, wherein the disease in which pulmonary surfactant and/or phosphodiesterase 5 (PDE5) activity is detrimental is selected from the group consisting of COPD, bronchitis, bronchial asthma, pulmonary fibroses, emphysema, interstitial pulmonary disorders, pneumonia, ALI, ARDS and asthma bronchiale.

The closest prior art of Wilkins et al (Clinical Techniques in Equine Practice (2003) pages 56-66) teaches the intravenous administration of sildenafil for the removal of vascular resistance in pulmonary tissue. Wilkins et al also teaches the administration of exogenous surfactants for treatment of conditions arising from surfactant dysfunction, such as RDS. However, the prior art does not teach or make obvious the intratracheal or intrabronchial administration of Lusupultide and Sildenafil, administered simultaneously or in succession for the treatment of conditions wherein PDE5 activity or

Art Unit: 1654

surfactant malfunction is detrimental, such as in COPD, bronchitis, bronchial asthma, pulmonary fibroses, emphysema, interstitial pulmonary disorders, pneumonia, ALI, ARDS and asthma bronchiale.

Thus, the claimed invention is both novel and unobvious over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1654



Hemant Khanna Ph.D.
March 28, 2007



Cecilia J. Tsang
Supervisory Patent Examiner
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